

Application No.: 10/582,006
Filing Date: June 7, 2006

REMARKS

Claims 1-24 and 32-34 are now pending. Claim 1 has been amended to include the subject matter of original Claim 4. Claims 2 and 3 have been amended to delete the superfluous term "fragment." New Claim 34 is directed to subject matter that was indicated as allowable by the Examiner. Claims 25-30 have been deleted without prejudice or disclaimer.

Applicants gratefully acknowledge the Examiner's indication that Claim 23 is allowed and Claim 32 contains allowable subject matter. Claims 32 and 33 have been amended to include the subject matter of Claim 26. The Applicants also appreciate the Examiner's indication of additional allowable subject matter.

Applicants traverse the rejection of Claims 1-3, 12-22, 26, and 30-31 under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants respectfully submit that the amendments to Claims 2 and 3 address this rejection with respect to the phrase "said antibody fragment" without limiting the scope of the claims.

Applicants' amendment to Claim 1 addresses the issue raised by the Office with respect to the phrase "fully humanized."

Applicants have amended Claims 12 and 13 to refer to the CDR regions (CDR1 and CDR2) by specific SEQ ID NO., thereby addressing the Office's rejection. Thus, Applicants respectfully request withdrawal of this rejection.

Applicants traverse the rejection of Claims 4-12 and 14-22 under 35 U.S.C. § 112, first paragraph as lacking written description.

According to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, para. 1 ("the Guidelines"), in MPEP § 2163 (I.)(A.), "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." In addition, according to the Guidelines, MPEP § 2163 (III.)(A.), the Office must "Establish a *prima facie* case by providing reasons why a person skilled in the art **at the time the application was filed** would not have recognized that the inventor was in possession of the invention (emphasis added)."

Applicants respectfully submit that the Office has not complied with the timing requirement, and thus has not met its burden of establishing a *prima facie* case of lack of written description. The Office relied on an excerpt from a textbook (Paul) published at least 10 years

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prior to the filing date of the present application as evidence to support the assertion that the "amino acid sequences and conformations of each of the heavy and light chain CDRs are critical to maintaining the antigen binding specificity and affinity, which is characteristic of the parent immunoglobulin." Specifically, the Office did not provide reasons why skilled person in the art **at the time the application was filed** would not have recognized that the inventor was in possession of the invention, but rather relied on an excerpt published 10 years before the application was filed.

Further, Applicants respectfully submit that the Office has not provided sufficient evidence or reasons why a person skilled in the art would not have recognized that the inventors were in possession of the claimed invention. Specifically, the present application states in paragraph 46: "the CDR3 regions, and more particularly the heavy chain CDR3, are largely responsible for antibody specificity." In addition, the present application states in paragraph 55 that antibodies may include "at least the heavy chain CDR3 region of the 5H2 antibody...." Further, antibodies have been contemplated, for example in paragraph 54, "in which the Fc and/or FR and/or CDR1 and/or CDR2 and/or light chain CDR3 regions of the 5H2 antibody...have been replaced by homologous human or non-human sequence." Please also see paragraph 56. Applicants respectfully submit that the Office has not established a *prima facie* case of lack of written description for the rejected claims and thus, the Applicants respectfully request withdrawal of this rejection.

Applicants traverse the rejections of a) Claims 1-3, 17-20 and 22 under 35 U.S.C. § 102(b) as being anticipated by Pupo-Antunez; b) Claims 14-16 under 35 U.S.C. § 103(a) over Pupo-Antunez in view of Gavilondo; and c) Claims 26, and 30-31 under 35 U.S.C. § 103(a) over Schofield in view of Scherer with evidence by Sanna. Applicants respectfully submit that Claim 4 was not rejected and the subject matter of Claim 4 is now included in Claim 1. Therefore, Applicants respectfully request withdrawal of these rejections with respect to those claims that are dependent upon Claim 1. Claims 26 and 30-31 have been deleted, thus rendering moot the rejection as to these claims.

In view of the foregoing comments, it is respectfully submitted that the present application is fully in condition for allowance, and such action is earnestly solicited. If any

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questions remain, however, the Examiner is cordially invited to contact the undersigned attorney so that any such matters may be promptly resolved.

No Disclaimers or Disavowals


Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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